APR 12 2012

5. 510(K) SUMMARY

Applicant:	Focus Medical 23 Francis J. Clarke Circle Bethel, CT 06801 203-730-8885
Manufacturer:	Focus Medical 23 Francis J. Clarke Circle Bethel, CT 06801
Contact Person:	Mr. John B. Lee, Jr. President Focus Medical
Name of the Device:	NaturaLase CO2 Laser Regulation Number: 21 CFR 878.4810 Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology Regulatory Class: Class II Product Code: ONG
Predicate Device:	Lutronic Mosaic eCO2 Laser System (K080496)
Device Description:	The NaturaLase CO2 is an RF excited CO2 laser. The laser energy is delivered through an articulated arm and with a scanner that distributes the laser energy on the skin in a controlled way with uniform distribution. The scanner design allows the system to ablate small micro spots of tissue. The system has the ability to deliver micro spots with a size of 120 microns and up to 45 mJ of optical energy per micro spot.
Indications for Use:	**The NaturaLase CO2 Laser System is indicated for use in dermatological procedures requiring ablation (removal), resurfacing or coagulation of soft tissue.**
Substantial Equivalence:	The NaturaLase CO2 has the same intended use as the predicate device-Lutronic Mosaic eCO2 Laser System (K080496). It uses the same fundamental technology as the predicate device. Both systems use similar RF excited CO2 laser tubes with the energy delivered through an articulated arm and a scanner. Both use a 120 micron micro spot and have various scanner patterns that deliver ablative fractional resurfacing.
Histology Data:	Histology data was collected to demonstrate the performance of the laser. The study included laser treatment of human skin to verify the healing rate and the characteristics of the micro spot at various energy settings. Punch biopsies were used to measure spot size, treatment depth and the healing process over a three week period. The wounds and the healing process showed an excellent correlation with literature and with the control laser.
Conclusion:	The specifications, indications for use and performance of the NaturaLase CO2 Laser is substantially equivalent to the legally marketed predicate device. Histology data confirmed the treatment parameters and the safety and effectiveness of the laser. It raises no new issues of safety and effectiveness and should be approved for marketing under the general controls provisions of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Focus Medical
% Mr. John B. Lee, Jr.
President
23 Francis J. Clarke Circle
Bethel, Connecticut 06801

APR 12 2012

Re: K110333
Trade/Device Name: NaturaLase CO2 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ONG
Dated: March 20, 2012
Received: April 3, 2012

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Dir Ltr

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Intended Use Statement

The NaturaLase CO2 Laser System is indicated for use in dermatological procedures requiring ablation (removal), resurfacing or coagulation of soft tissue.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) The

Neil R Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110333